

CHAPTER 61-02-08 TELEPHARMACY RULES

Section

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61-02-08-01. Purpose and scope.

1. The state board of pharmacy is responsible for maintaining, continuing, and enhancing the development of the education and professional role of the pharmacist for the protection of the health, welfare, and safety of the citizens of North Dakota.
2. Rural North Dakota is facing an accessibility problem due to closing pharmacies.
3. In order to maintain or make pharmacy services available in areas that have lost their pharmacies or are in jeopardy of losing their pharmacies, rules are necessary to permit telepharmacies.
4. This chapter applies to central pharmacies, each with one or more remote sites. Both the central pharmacy and remote site may be located within North Dakota, either the remote site or the central pharmacy, may be located in a contiguous state.

History: Effective October 1, 2001; amended effective December 1, 2003; January 1, 2005.

General Authority: NDCC 43-15-10(7)(9)(11)(12)(14)(19)

Law Implemented: NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

61-02-08-02. Definitions.

1. "Remote site" means a pharmacy staffed by a registered pharmacy technician with access to its main pharmacy and registered pharmacists by computer link, videolink, and audiolink while open.
2. "Satellite consultation site" means a telepharmacy where any filled prescription ready for dispensing is prepared at another pharmacy and delivered to the satellite for dispensing via computer, videolink, and audiolink to the main pharmacy and a licensed pharmacist.

3. "Telepharmacy" means a central pharmacy with one or more remote sites in which all sites are connected via computer link, videolink, and audiolink.
4. "Telepharmacy in hospitals" means a central hospital pharmacy with one or more remote sites in which all sites are connected via computer, videolink, and audiolink.

History: Effective October 1, 2001; amended effective December 1, 2003.

General Authority: NDCC 43-15-10(7)(9)(11)(12)(14)(19)

Law Implemented: NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

61-02-08-03. Operations.

1. A remote site shall comply with North Dakota Century Code section 43-15-35 governing requirements for a permit to operate a pharmacy. The remote site is considered to be under the personal charge of the pharmacist at the central pharmacy.
2. A remote site shall be connected to its central pharmacy via computer link, videolink, and audiolink.
3. A remote site shall use its central pharmacy's central processing unit.
 - a. Consecutive prescription numbers and all prescription records must be maintained at the central pharmacy.
 - b. Prescriptions filled at the remote site must be distinguishable on records from those filled at the central pharmacy.
 - c. Daily reports must be separated for the central pharmacy and the remote site but must be maintained at the central pharmacy.
 - d. Pharmacies must be able to generate labels from the central pharmacy or at the remote site.
 - e. All prescriptions distributed at the remote site must have a label that meets requirements set forth in chapter 61-04-06 attached to the final drug container before the pharmacist verifies the dispensing process.
4. A pharmacist at the central pharmacy must approve each prescription before it leaves the remote site.
 - a. Dispensing is considered to be done at the central pharmacy.
 - b. Both the pharmacist's and the technician's initials must appear on the fill screen, patient profile, and label.

- c. A pharmacist shall compare via videolink the stock bottle, drug dispensed, and strength. The entire label must be checked for accuracy on the videolink.
- 5. Counseling must be done by a pharmacist via videolink and audiolink. The pharmacist must counsel the patient or the patient's agent on all new prescriptions and refills.
- 6. A pharmacist must complete monthly inspections of the remote site. Inspection criteria must be included in the policies and procedures for the site. The inspection reports must be maintained until the next state board of pharmacy inspection.
- 7. The remote site may have a prescription inventory. Controlled substances shall be kept at the remote site in accordance with North Dakota Century Code chapter 19-03.1, the Uniform Controlled Substances Act.
 - a. If controlled substances are kept, the remote site must be registered with the drug enforcement administration and obtain its own drug enforcement administration number.
 - b. All records must be stored at the central pharmacy, except those required by the drug enforcement administration to be at the drug enforcement administration-registered site.
- 8. There must be policies and procedures in place to ensure the safe and effective distribution of pharmaceutical products and delivery of required pharmaceutical care. There must be an ongoing review of incident reports and outcomes, with appropriate corrective action taken when necessary, to ensure there is no abnormal frequency of errors in dispensing drugs or devices.
- 9. The telepharmacy location must be in compliance with chapter 61-02-02, building standards for pharmacies; chapter 61-02-03, security standards for pharmacies; and chapter 61-02-04, sanitary standards for pharmacies; except as otherwise provided in this chapter.
- 10. Dispensing and consultation may be done when the registered pharmacy technician is not present, under the following circumstances:
 - a. The prescription has been prepared by the registered pharmacy technician and checked by the licensed pharmacist.
 - b. The prescription area is locked.
 - c. A separate locked drawer or cabinet is maintained for prescriptions ready for dispensing.

- d. A log is maintained by the registered pharmacy technician of prescriptions placed in the locked drawer or cabinet.
 - e. A record must be made by the pharmacist as to the date and time at which dispensing and counseling occurs.
 - f. Supportive personnel, trained in the use of the audiolink and videolink, to the licensed pharmacist, are on hand, to assist the patients.
 - g. The patients receive their prescriptions as they are being counseled by the licensed pharmacist.
11. The permitholder or the pharmacist in charge of the central pharmacy must apply for a permit for the remote site. A class K permit is established under section 61-02-01-01 for the purpose of conducting a telepharmacy. These permits are issued to a remote site connected to a central pharmacy via computer link, videolink, and audiolink.

History: Effective October 1, 2001; amended effective December 1, 2003.

General Authority: NDCC 43-15-10(7)(9)(11)(12)(14)(19)

Law Implemented: NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

61-02-08-04. Rule exceptions. To the extent of a conflict with any provision of this title, the provisions of this chapter govern with respect to a telepharmacy and remote site operating in compliance with this chapter. With the following conditions, this chapter is an exception to the following rules:

- 1. Pharmacist on duty under section 61-02-01-13. The remote site must have a registered pharmacy technician present and a working computer link, videolink, and audiolink to a pharmacist at the central pharmacy to have the prescription area open. The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is at the remote site.
 - a. The technician must be registered with the state board of pharmacy and have at least one year of work experience as a North Dakota-registered pharmacy technician.
 - b. The technician must be a graduate of an approved pharmacy technician education program or must make application to the board, and must demonstrate knowledge and experience in preparation of prescriptions for dispensing and working with patients.
 - c. The technician will be subject to all rules in chapter 61-02-07.1, excluding the ratio of pharmacists to pharmacy technicians. A pharmacist may oversee no more than four remote sites. As

dispensing is considered done by the pharmacist, the pharmacist will be responsible for and held accountable for the remote site.

2. Security standards for pharmacies under subsections 3, 4, 6, 7, and 9 of section 61-02-03-01. The pharmacy technician may unlock the prescription and storage areas. While the technician is on duty, the prescription area may remain open.
3. Input of drug information into electronic data processing equipment under section 61-02-06-01. The input of drug information shall be done by a pharmacist at the central pharmacy or, if entered by the technician at the remote site, must be verified by a pharmacist.
 - a. New prescriptions may be received and entered at the central pharmacy with a label printed at the remote site.
 - b. New prescriptions received at the remote site may be entered into the remote computer system with all verification, interaction checking, and profile review the responsibility of the pharmacist at the central pharmacy.

History: Effective October 1, 2001.

General Authority: NDCC 43-15-10(7)(9)(11)(12)(14)(19)

Law Implemented: NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

61-02-08-05. Suspension and termination.

1. The board may suspend immediately the permit of any class K pharmacy if a danger to the public exists.
2. The board may terminate all of the class K permits pursuant to North Dakota Century Code chapter 28-32. A sixty-day notice will be sent to the pharmacist in charge of each.

History: Effective October 1, 2001; amended effective January 1, 2004.

General Authority: NDCC 43-15-10(7)(9)(11)(12)(14)(19)

Law Implemented: NDCC 43-15-28.1

61-02-08-06. Expiration. Repealed effective July 1, 2005.

61-02-08-07. Telepharmacy satellite consultation sites.

1. These sites have no prescription inventory.
2. Only filled prescriptions, filled at the central pharmacy, with final patient labeling attached are allowed at these sites.

3. These sites may be controlled by supportive personnel who have been trained in the use of the patient counseling audiolink and videolink necessary for the dispensing and consultation to occur.
4. The supportive personnel assist the patient in accessing the pharmacist via the audiolink and videolink.
5. Prescription refill requests may be communicated to this site by the patient or the patient's agent.
6. Original written prescriptions may be brought to these sites by the patient or the patient's agent for faxing, scanning, and transmitting to the central pharmacy.
7. No prescription or refill communicated from practitioners may be received at these sites.
8. No drug enforcement administration number is necessary as only filled prescriptions will be at the site.
9. Security of filled prescriptions must be maintained by a separate locked drawer or cabinet.
10. A record must be made by the pharmacist as to the date and time at which dispensing and counseling occurred.

History: Effective December 1, 2003.

General Authority: NDCC 43-15-10(7)(9)(11)(12)(14)(19)

Law Implemented: NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

61-02-08-08. Telepharmacy in hospitals.

1. The supervision required in subsection 3 of section 61-07-01-04 may be accomplished via audiolink, videolink, and computer link, if the hospital has a registered pharmacy technician on duty meeting the qualifications of subsection 1 of section 61-02-08-04.
2. No prescription order may be released for administration to a patient until approved by a pharmacist via the audiolink, videolink, and computer link.
3. The policy and procedures of the hospital pharmacy must address all aspects of the telepharmacy operation, including control of the pharmacy by the registered pharmacy technician in the absence of the pharmacist.
4. Contractual arrangements must be in place for the supervision of the technician by either the consultant pharmacist, another hospital

pharmacy with adequate staffing, or a contracted pharmacist providing coverage when pharmacist staffing is not provided at the hospital.

History: Effective December 1, 2003.

General Authority: NDCC 43-15-10(7)(9)(11)(12)(14)(19)

Law Implemented: NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

61-02-08-09. Telepharmacy satellite remote dispensing machine sites.

1. These sites have prescription inventory, which is secured in an automated dispensing device connected to the central processing unit at the central pharmacy.
2. A pharmacist must approve all prescription orders before they are released from the automated dispensing device.
3. Dispensing and counseling are performed by the licensed pharmacist at the central site via audiolink and videolink.

History: Effective December 1, 2003.

General Authority: NDCC 43-15-10(7)(9)(11)(12)(14)(19)

Law Implemented: NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35